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10/533,289	04/29/2005	Lars Martensson	1027651-000272	6042
21839	7590	08/14/2008	EXAMINER	
BUCHANAN, INGERSOLL & ROONEY PC			YOO, REGINA M	
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ALEXANDRIA, VA 22313-1404			ART UNIT	PAPER NUMBER
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			08/14/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/533,289	MARTENSSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	REGINA YOO	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 03 June 2008.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-35 is/are pending in the application.  
 4a) Of the above claim(s) 20-35 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-19 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

### ***Response to Amendment***

The amendment filed on 6/03/2008 has been received and claims 1-35 are pending.

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I in the reply filed on 6/03/2008 is acknowledged. The traversal is on the ground(s) that "there exists no rule or statute supporting the view that a prior art reference disclosing a special technical feature commonly recited in independent claims of a U.S. National Stage application properly establishes lack of unity of invention". This is not found persuasive because a lack of unity restriction for a U.S. national stage application under 35 U.S.C 371 follows statutes such as 37 CFR 1.499. Also see the following paragraphs:

"Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted."

In addition, the absence of a lack of unity of invention requirement by the International Searching Authority does not preclude a lack of unity of invention requirement in the national stage application.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7 and 13-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Zelina (20020159915).

As to Claims 1 and 3, Zelina ('915) discloses a device for sterilization in production of packages (120) (see entire document, particularly Figure 8), which is adapted for sterilization with a gaseous sterilizing agent in the form of gaseous hydrogen peroxide (see entire document, particularly Abstract) kept in the gaseous phase throughout the sterilization process (see entire document, particularly p.5 [0061]), said device comprising a heating zone (170), a sterilization zone (11), a venting zone (182) and means (10, 172) for maintaining a higher pressure in the sterilization zone (11) than in the heating zone (170) and venting zone (180) (see Figure 8 and [0063]-[0064], where the venting zone is at negative pressure and the heating zone is deemed to be at ambient/atmospheric pressure as there is not a component affecting pressure within, while the sterilization zone is comprised of means to supply gaseous sterilant that produces a positive/higher pressure; thus, the sterilization zone is deemed to be at the higher pressure than the other adjacent zones especially according to the teaching

in [0064] where there is no exhaust (i.e. there is no 174 or 176); in addition p.6 [0072] also teaches a reduced pressure zone prior to the sterilization zone).

As to Claim 2, Zelina ('915) discloses that said zones are separated from each other by partitionings having openings for the passage of packages (see Figures 1 and 8).

As to Claim 4, Zelina ('915) discloses that the device is adapted to sterilize packages (120) before filling of the packages (120), said packages (120) having an open end (123, 134) and a closed end (132) (see entire document, particularly Figures 1 and 8).

As to Claim 5, Zelina ('915) discloses that the heating zone (170) comprises means (171) for heating the packages (120) to a temperature above a dew point of the sterilizing agent used in the sterilization zone (11) (see entire document, particularly Figure 8 and p. 5 [0062]).

As to Claim 6, Zelina ('915) discloses that the venting zone (182) comprises means (183, 184) for venting away the sterilizing agent used in the sterilization zone (11) from the packages (120) after sterilization (see entire document, particularly Figure 8 and p. 6 [0064]).

As to Claim 7, Zelina ('915) discloses that the device is further comprised of means (172, 174) for controlling a flow of gaseous sterilizing agent in the sterilization zone (11), such that the gaseous sterilizing agent flows essentially in a direction from the open end (123, 134) of the packages (120) towards the closed end (132) of the packages (120) (see entire document, particularly Figure 8, p. 5 [0063] and p. 6 [0067]).

As to Claim 13, Zelina ('915) discloses that the device is further comprised of an entry temperature sensor for sensing the temperature of the packages (120) before entering the sterilization zone (11) (see p. 5 [0059] where it is deemed that the temperature of individual package is measured before the entry into the sterilization zone so that there is sufficient notice by control system to modify the operation of the vaporizer and/or residence time of the packages in the sterilization).

As to Claim 14, Zelina ('915) discloses that the device is further comprised of a feedback circuit (see p. 5 [0057]-[0059] and [0061]) for controlling the heating in the sterilization zone (11). Zelina ('915) also teach that the temperature of individual incoming packages is also measured and monitored to ensure that the condensation does not occur by using the feedback circuit to change various operating components/parameters (see p. 5 [0059]). It is deemed that this feedback circuit is capable of controlling the heating (171) in the heating zone (170) based on the temperature of the packages (120) being measured.

As to Claim 15, Zelina ('915) discloses that the device is further comprised of a condensation detector (152, 153) for detecting condensation in the sterilization zone (11) (see entire document, particularly p.5 [0057]-[0061] where a dew point or humidity sensor is a condensation detector).

As to Claim 16, the device of Zelina ('915) is fully capable of sterilizing itself internally when the device is operated without the packages (120).

As to Claim 17, Zelina ('915) discloses that the device is comprised means (171) for heating the interior of the device (see Figure 8).

As to Claim 18, Zelina ('915) discloses that the device is comprised of a unit (10) for production of the gaseous sterilizing agent (see Figure 8 and p. 5 [0060]).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 8 and 12 are rejected under 35 U.S.C. 103(a) as obvious over Zelina (20020159915).

Zelina ('915) is relied upon for disclosure described in the rejection of claims 4 and 7 under 35 U.S.C. 102(b).

As to Claim 8, while Zelina ('915) does not appear to specifically teach in the embodiment shown in Figure 8 that the means for controlling the flow of gaseous sterilizing agent are arranged to introduce the gaseous sterilizing agent in a top portion of the sterilization zone (11) and to evacuate the gaseous sterilizing agent in a bottom

portion of the sterilization zone (11), maintaining a flow of gaseous sterilizing agent essentially from top to bottom, Zelina ('915) discloses an alternate embodiment wherein the means (14, 10, 200) for controlling the flow of gaseous sterilizing agent are arranged to introduce the gaseous sterilizing agent in a top portion of the sterilization zone (11) and to evacuate the gaseous sterilizing agent in a bottom portion of the sterilization zone (11), maintaining a flow of gaseous sterilizing agent essentially from top to bottom (see Figure 11).

Thus, it would have been well within the purview of one of ordinary skill in this art at the time of invention to provide the configuration of means for flowing the sterilizing agent shown in Figure 11 to the embodiment disclosed in Figure 8 as a known alternate configuration to supply the sterilizing agent. Only the expected results would be attained.

As to Claim 12, while Zelina ('915) does not appear to specifically teach in the embodiment shown in Figure 8 that the device is further comprises a package heating temperature sensor for sensing the temperature of the packages entering the heating zone, Zelina ('915) teaches that the avoidance of condensation of the hydrogen peroxide vapor on the packages is important (see p. 5 [0061]) and provides means to ensure that the temperature of the packages, through heating in the heating zone (170) prior to entering the sterilization zone (11), is at a sufficient temperature that the surfaces of the packages are at or above the temperature of the sterilization zone when the packages enter the sterilization zone, as well as while residing in the sterilization

zone (see Figure 11), so as to avoid condensation occurring on the surface of the packages (see p. 5 [0059] and [0062]). Zelina ('915) further teaches that the temperature of individual package is measured and this information fed to the control system so as to modify the operation parameters of various components within the device (see p. 5 [0059]).

Thus, it would have been well within the purview of one of ordinary skill in this art at the time of invention to also provide a temperature sensor at the entry to the heating zone in the device of Zelina in order to sense the temperature of packages entering the heating zone so that the operation of heating means in the heating zone is adjusted for further/optimized control according to initial package temperature to ensure that appropriate package temperature for sterilization will be achieved within the residence time allotted for the operation/processing in the heating zone. Only the expected results would be attained.

7. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zelina (20020159915) as applied to claim 4 above, and further in view of Fotti (4992247).

Zelina ('915) is relied upon for disclosure described in the rejection of claim 4 under 35 U.S.C. 102(b).

Zelina ('915) does not appear to specifically teach that the device is further comprised of means for controlling a venting air flow in the venting zone, such that the venting air flows essentially in a direction from the open end of the packages towards

the closed end of the packages nor that the means for controlling the flow of venting air are arranged to introduce the venting air in a top portion of the venting zone and to evacuate the venting air in a bottom portion of the venting zone, maintaining a flow of venting air essentially from top to bottom.

It was known in the art at the time of invention to provide a device for sterilization in production of packages using gaseous sterilizing agent with means for controlling a venting air flow in the venting zone, such that the venting air flows essentially in a direction from the open end of the packages towards the closed end of the packages where the means for controlling the flow of venting air are arranged to introduce the venting air in a top portion of the venting zone and to evacuate the venting air in a bottom portion of the venting zone, maintaining a flow of venting air essentially from top to bottom.

Fotti ('247) discloses that a device (10) for sterilization in production of packages using gaseous sterilizing agent is further comprised of means (48, 54) for controlling a venting air flow in the venting zone (52), such that the venting air flows essentially in a direction from the open end of the packages (38) towards the closed end of the packages (38) (see entire document, particularly Figure 1 and Col. 3 lines 12-20), wherein means (48, 54) for controlling the flow of venting air are arranged to introduce the venting air in a top portion (48) of the venting zone (52) and to evacuate the venting air in a bottom portion (62, 64) of the venting zone (52), maintaining a flow of venting air essentially from top to bottom (see Figure 1) in order to remove a condensate mixture from the surface of packages (see entire document, particularly Col. 3 lines 12-15).

It would have been obvious to one of ordinary skill in this art at the time of invention to provide means for controlling a venting air flow in the venting zone, such that the venting air flows essentially in a direction from the open end of the packages towards the closed end of the packages in the device of Zelina in order to remove the sterilizing agent from the packages as shown by Fotti.

Thus, Claims 9-10 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Zelina ('915) and Fotti ('247).

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zelina (20020159915) as applied to claim 4 above, and further in view of Hanley (6565802). Zelina ('915) is relied upon for disclosure described in the rejection of claim 4 under 35 U.S.C. 102(b).

While Zelina ('915) discloses a device for sterilization with temperature sensors in the device, Zelina ('915) does not appear to specifically teach that the device is further comprised of an ambient temperature sensor for sensing the ambient temperature outside the device.

It was well known in the art at the time of invention to provide a temperature sensor that is located outside a device for sterilization for sensing the ambient temperature. Hanley ('802) exemplifies a sterilization device (10) comprised of a temperature sensor (145) located outside the device (10) (see Figures 1-2) in order to measure the ambient temperature of the outside environment and to provide an indication of the air temperature being delivered to within the device so that the

operation of the device will be adjusted accordingly (see entire document, particularly Col. 11 lines 2-16).

It would have been obvious to one of ordinary skill in this art at the time of invention to provide an ambient temperature sensor outside the device of Zelina in order to measure the ambient temperature to provide an indication of temperature of the material (such as air or articles that are in equilibrium with the ambient atmosphere) being delivered into the device so as to adjust the operating parameters accordingly for optimized operation of the device as exemplified by Hanley.

Thus, Claim 11 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Zelina ('915) and Hanley ('802).

9. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zelina (20020159915) as applied to claim 1 above, and further in view of Catelli (5848515).

Zelina ('915) is relied upon for disclosure described in the rejection of claim 1 under 35 U.S.C. 102(b).

While Zelina ('915) discloses that the device is further comprised of a filling zone (190) (see Figure 8), Zelina ('915) does not appear to specifically teach that the filling zone is comprised of means for maintaining a higher pressure than in the venting zone.

It was well known in the art at the time of invention to provide a higher pressure in the filling zone of a bottling device that also employs a sterilization zone and a venting zone. Catelli ('515) exemplifies a device (1) comprised of a sterilization zone (10a), a venting zone (20) and a filling zone (30), as well as means (13, 14) for

maintaining a higher pressure in the sterilization zone (10a) and in filling zone (30) in order to keep each of the zones sterile (see entire document, particularly Col. 3 lines 13-17 and Col. 4 lines 64-67, where these means are independently controllable as to adjust the pressure within each zone and thus, is able to produce a higher pressure in the sterilization zone and filling zone compared to the venting zone).

It would have been obvious to one of ordinary skill in this art at the time of invention to provide the means to maintaining a higher pressure in the filling zone than in the venting zone of Zelina in order to keep the filling zone sterile so that the final product will not be contaminated as exemplified by Catelli.

Thus, Claim 19 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Zelina ('915) and Catelli ('515).

### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/531297. Although the conflicting claims are not identical, they are not patentably distinct from each other because the device of the co-pending application also claims a device with same features.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-20 of U.S. Patent No. 6692684 in view of Zelina (20020159915). While Pat. 6692684 discloses a device for sterilization in production of packages comprised of a heating zone and a sterilization zone, it does not appear to specifically teach that the second heating station is comprised of an exhaust means to vent the sterilizing agent or that the device is comprised of means for maintaining a higher pressure in the sterilization zone than in the heating zone and venting zone. Zelina ('915) exemplifies an exhaust means in a second heating zone to provide a venting zone in the device and means for maintaining a higher pressure in the sterilization zone than in the heating zone and venting zone, as described/discussed in rejections above. Thus, it was well known in the art at the time of invention to provide these missing features in a device for sterilization in production of packages and it

would have been obvious to one of ordinary skill in this art at the time of invention to provide these features in the device of the Pat. No. 6692684 in order to vent the gaseous sterilizing agent from the packages and to prevent contaminants from entering the sterilization zone from the other adjacent zones as exemplified by Zelina.

### ***Response to Arguments***

13. Applicant's arguments filed 6/03/2008 have been fully considered but they are not persuasive.

As to Applicant's argument regarding the rejections based on the reference of Zelina, Examiner would indicate that the rejections above is based on the disclosure in p.6 last five lines of paragraph [0064], where Zelina teaches that the exhaust lines (and thus the pump 176 as well) are not present in the decontamination chamber so that the aeration chamber is utilized to remove the sterilant vapor from the packages. Thus, Examiner would maintain that the pressure within the sterilization zone is maintained at a higher pressure than in the heating zone and venting zone.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REGINA YOO whose telephone number is (571)272-6690. The examiner can normally be reached on Monday-Friday, 10:00 am - 7:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth L McKane/  
Primary Examiner, Art Unit 1797

RY